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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,911

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Morten Mernoe

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EXAMINER

MEDWAY, SCOTT J

ART UNIT

PAPER NUMBER

3763

NOTIFICATION DATE

DELIVERY MODE

02/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/587,911	Applicant(s) MERNOE, MORTEN	
	Examiner SCOTT MEDWAY	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/30/2006,08/30/2007,09/24/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In the Preliminary Amendment dated 07/28/2006, clams 1-49 have been cancelled and new claims 50-57 have been added. Thus, claims 50-57 are pending.

Specification

1. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the Specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the Specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o). Also see MPEP 2181 (Rev. 1, Feb. 2000).

Appropriate correction is required.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

3. Claim 50 is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for reasons set forth above in the objection to the specification.

Appropriate correction is required.

For the purposes of examination, the limitation "means for attaching said housing to the skin of a user of said device" in the claim is interpreted to be, for example, but not limited to, an adhesive means.

4. Claim 54 is objected to because of the following informalities: the abbreviation "POM," being somewhat vague, should be replaced by an indication of what it is intended to cover. For the purposes of examination, "POM" will be interpreted to mean polyoxymethylene. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty (U.S. Pat. 6,656,159 B2).

Regarding claims 50 and 51, Flaherty discloses a disposable, wearable medicine dispensing device (see Fig. 1) comprising: a housing (20); means for attaching the housing to the skin such as an adhesive (col. 9, lines 36-38); a medicine container (32) disposed in the housing; a flexible piston rod (202, 606) shown in Fig. 4 to have an outer thread pattern; a ratchet wheel (502) having an inner thread pattern on a central aperture to mate with the outer thread pattern of the piston rod; a pivotable body (504); spring device (510) to bias the pivotable body; and actuation system comprising a thread member (508) and a battery powered actuator (80) to apply a tension force to the thread. A pawl member (216, 256) is additionally disposed on the pivotable body.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Hansen et al (U.S. Pub. 2002/0007154 A1, hereinafter "Hansen").

Regarding claims 52 and 53, Flaherty discloses the invention substantially as claimed except for the piston rod comprising rod segments hinged together where the outer thread pattern is on the rod segments and the segments are connected by hinges. Hansen discloses an injection device comprising a piston rod (1) which is actuated by a ratchet (3) and has threads on a portion of its segments (see Fig. 4), and where hinges formed of bendable material cause the segments to bend with respect to one another (see Fig. 4). It would have been obvious for one of ordinary skill in the art at the time of the invention to substitute the uniform rod of Flaherty with the segmented and flexible rod of Hansen so as to make a device performing the same function but being substantially smaller on the body, and having a piston that can bend so as to decrease the amount of space needed to operate it would be sufficient to accomplish this task.

10. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Fogarty (U.S. Pat. 4,315,512).

Regarding claim 54, the combination of Flaherty and Hansen renders substantially unpatentable the invention as claimed except for the bendable material of the piston being nylon. Fogarty discloses a piston in a medical device where the piston

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is made from nylon (col. 4, line 1). It would have been obvious for one of ordinary skill in the art at the time of the invention to use nylon as taught by Fogarty in the piston of Flaherty, since it is known and disclosed by Fogarty that nylon is a strong and flexible material, and its use would represent prompting the use of a known material on the basis of its suitability for a device's intended use.

11. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Hansen et al (U.S. Pub. 2002/0007154 A1, hereinafter "Hansen"), further in view of Brown (U.S. Pat. 2,695,023).

Regarding claim 55, the combination of Flaherty and Hansen renders substantially unpatentable the invention as claimed except for the outer thread pattern being a discontinuous thread pattern. Brown discloses a hypodermic syringe having detents (44, 45, 46, 47, 48) on an outer surface of the rod where the detents are situated in discontinuous groups. Since Brown discloses that the groups are for selectively adjusting the amount of material to be pushed by the piston rod from the syringe, it would have been obvious for one of ordinary skill in the art at the time of the invention to consider using a discontinuous thread pattern taught by Brown in the invention of Flaherty in view of Hansen so as to make a piston rod capable of being coupled to an actuator so as to provide a selective or incremental amount of material to be infused to the body.

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12. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Albisser et al (U.S. Pat. 6,752,789 B2, hereinafter "Albisser").

Regarding claims 56 and 57, it is noted that Flaherty discloses the invention substantially as claimed except for the battery powered actuator being a solenoid. Albisser discloses a syringe plunger mechanism being powered by an actuator where the actuator is a solenoid (col. 3, lines 29-33). It would have been obvious for one of ordinary skill in the art at the time of the invention to implement a solenoid as a battery powered actuator as taught by Albisser in the device of Flaherty, since solenoids are well-known in the art of battery-powered syringe mechanisms to allow for controlled or selective infusion of drugs.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant is directed to the *Notice of References Cited*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/
Examiner, AU 3763
02/13/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763